**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF TEXAS**
**DALLAS DIVISION**

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| REBECCA FELDMAN,<br><br>Plaintiff,<br><br>v.<br><br>STRYKER CORPORATION; HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS; AAP BIOMATERIALS GMBH; AAP IMPLANTATE AG; and AAP IMPLANTS, INC.,<br><br>Defendants. | CIVIL ACTION NO. _____<br><br>**COMPLAINT AND JURY DEMAND** |

## COMPLAINT

Plaintiff Rebecca Feldman, by and through her undersigned counsel, hereby files this Complaint and alleges against Defendants as follows:

## PARTIES, JURISDICTION, AND VENUE

1. At all times relevant to this Complaint, Rebecca Feldman has been and continues to be a resident and citizen of Paris, Texas.

2. Defendant Stryker Corporation is a Michigan corporation with its principal place of business located at 2825 Airview Boulevard, Portage, Michigan 49002. Defendant Stryker Corporation may be served through its agent of record, The Corporation Company, 40600 Ann Arbor Road E, Suite 201, Plymouth, Michigan 48170.

3. Defendant Howmedica Osteonics Corporation is a New Jersey corporation with its principal place of business located at 325 Corporate Boulevard, Mahwah, New Jersey 07430. Upon information and belief, Defendant Howmedica Osteonics is a wholly owned subsidiary of

Defendant Stryker Corporation and does business as Stryker Orthopaedics. Defendant Howmedica Osteonics Corporation may be served through its agent of record, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

4. Defendant aap Biomaterials GmbH is a German corporation with its principal place of business located at Lagerstraße 11-15, Dieburg, Germany 64807.

5. Defendant aap Implantate AG is a German corporation with its principal place of business located at Lorenzweg 5 12099, Berlin, Germany.

6. Defendant aap Implants, Inc. is the distribution company of aap Implantate AG for the North American market. Defendant aap Implants, Inc. may be served through its agent of record, Incorporating Services, Ltd., 3500 S. Dupont Highway, Dover, Delaware 19901.

7. At all relevant times, Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

8. Each Defendant was involved, either directly or as described in the paragraph above, in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the Simplex HV bone cement, as well as monitoring and reporting adverse events.

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Ms. Feldman resides.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Ms. Feldman's claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

## BACKGROUND

11. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

12. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Knee replacement technology can provide a solution to the pain and restore basic function to those implanted. The knee replacement implants designed and approved in the 1990s met the goals of reducing pain and restoring function with low failure rates.

13. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

14. In a total knee replacement surgery, sometimes referred to as "arthroplasty," physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and

thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

15. Bone cement, or epoxy, is used to attach components of the new artificial knee joint to the femur (thigh bone) and tibia (shin bone). Bone Cement includes a powder and a liquid that must be combined. Cement "viscosity" determines the handling and working properties of the cement. Bone cement may be divided into three types: low, medium, and high viscosity ("HV").

16. Defendants manufacture, market, and sell the "Simplex family of bone cements," including Simplex P and the Simplex HV bone cements.

17. Upon information and belief, Simplex P is a low or medium viscosity bone cement, also known as "non-HV." According to Stryker, as of 2008, Simplex P "emerged as the most used bone cement in the US" and "[n]o other bone cement has stronger survivorship than Simplex P."

18. Upon information and belief, prior to the release of Simplex HV, Defendants promoted their non-HV Simplex P bone cements as being stronger, safer, and more effective than HV bone cements manufactured and sold by other companies at that time.

19. In a 2008 brochure, Stryker explained the importance of viscosity by stating, "[t]he deeper cement penetrates into bone, the stronger the fixation and shear strength of the bond. HV cements cannot be pressurized into bone as well as medium viscosity cements."

20. Further, Stryker explained the concept of "creep" by stating, "[t]he physical behavior of bone cement has clinical significance in terms of mechanical fixation and loosening. Bone cements that creep too much may lead to *component shifting, loosening, and failure*." This section of the brochure was titled, "Creep Matters: Simplex [P] Creeps Less Than High Viscosity Cements."

21. Despite Stryker promoting that its non-HV cements were stronger, safer, and more effective than HV bone cements, Defendants devised a plan to design, manufacture, market, and sell their own HV bone cements.

22. Simplex HV bone cement, the product at issue, is a high viscosity cement. Simplex HV liquid when packed with Simplex HV cement powder forms the product Simplex HV Cement. Mixing the two separate components produces a ductile bone cement which, after hardening, fixes the implant and transfers stresses produced during movement to the bone.

23. Upon information and belief, Defendants received FDA clearance of the Simplex HV bone cement under the "510k" notification process. The basis for FDA clearance of Simplex HV bone cement was substantial similarity to prior bone cements. Consequently, Defendants received FDA 510(k) approval of the Simplex HV bone cement with only very limited, if any, testing of the new HV bone cement.

24. Defendants used the 510k approval process and claim that these HV bone cements are "substantially equivalent" to the non-HV cements that have been in use for decades. However, in fact—and as previously represented by Stryker—the HV cement was and is less effective, and more prone to component shifting, loosening, and failure than previously-approved bone cements.

25. According to the Orthopaedic Research Society, researchers found HV cement less effective than low- or medium-viscosity bone cement ("non-HV").

26. Further, according to a study in the *Journal of Arthroplasty*, researchers found that HV cement, including the Simplex HV bone cement, increases the risk of failure, even when used in combination with a previously well-performing implant.

27. The primary reason the Simplex HV bone cement fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the

implant-cement interface. Mechanical loosening means that the attachment between the artificial knee and the existing bone has become loose. Such loosening will eventually result in failure of the device. Mechanical loosening, as shown by recent studies, has occurred at a significantly increased rate in patients implanted with HV bone cement, including the Simplex HV bone cement.

28. A loose artificial knee generally causes pain and wearing away of the bone. It can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

29. Once the pain becomes unbearable or the individual loses function of the knee, another operation, often called a "revision surgery," may be required to remove the knee implant and replace it with a new one.

30. Revision surgeries on a failed total knee due to loosening often require reconstruction of the severe bone loss.

31. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including limitations in range of motion, the ability to walk, and even death.

32. Despite Defendants' knowledge of failures, Defendants continue to represent that its HV bone cements, including Simplex HV bone cement, are safe and effective. For instance, in 2014, Stryker promoted "Simplex HV" as "A New Level of Strength, Speed and Handling."

33. Although Stryker previously represented that HV bone cements are not as strong and effective because they do not penetrate the bone as well as Simplex P, Stryker suggests its internal test results show Simplex HV bone cement has a "statistically equivalent depth of intrusion compared to Simplex P." Further, Stryker states that "Simplex P and Simplex HV both achieve greater than the studies recommended 4mm depth of cement penetration into cancellous bone."

34. Defendants actively and aggressively marketed, promoted, and represented to doctors that Simplex HV could provide the speed and rapid mixing times of high-viscosity cement, while also marketing, promoting, and representing that Simplex HV was as strong, safe, and effective as non-HV cements.

35. Although Defendants knew about the high number of HV bone cement failures, including Simplex HV bone cement failures resulting in revision surgeries, Defendants failed to warn doctors, consumers and patients, and allowed, marketed, and promoted the defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, including Ms. Feldman and her physicians.

## CASE SPECIFIC FACTUAL ALLEGATIONS

36. On November 25, 2015, Rebecca Feldman underwent a right-sided TKA performed by Jay Donald Mabrey, M.D. at Baylor University Medical Center at Dallas.

37. In that procedure, Dr. Mabrey utilized Simplex HV bone cement to cement all components in Ms. Feldman's right knee.

38. On August 4, 2016, Dr. Mabrey conducted a follow-up appointment with Ms. Feldman in which Dr. Mabrey noticed mechanical loosening of Ms. Feldman's right prosthetic knee joint and noted symptoms are likely due to the Simplex HV cement used in her procedure.

39. On August 16, 2016, Dr. Mabrey conducted another follow-up appointment with Ms. Feldman and took a bone scan that revealed results "consistent with mechanical loosening of her prosthetic." Dr. Mabrey listed the diagnosis as "[m]echanical loosening of right knee prosthesis" and Ms. Feldman planned to later proceed with a revision of the right knee.

40. On October 19, 2016, Ms. Feldman underwent revision surgery due to loosening of her knee components caused by the defective Simplex HV bone cement implanted in her right

knee and debonding of Simplex HV bone cement at the tibial component. This surgery was performed by Dr. Mabrey at Baylor University Medical Center at Dallas.

**COUNT I**
**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

41. Ms. Feldman adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

42. At all times herein mentioned, Defendants are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributors of the Simplex HV bone cement, which is defective and unreasonably dangerous.

43. The Simplex HV bone cement is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. The Simplex HV bone cement is defective in design because it lacks efficacy, has a high failure rate, poses a greater likelihood of injury, is more dangerous than other available bone cements indicated for similar conditions and uses, and the utility of the Simplex HV bone cement does not outweigh its risks.

44. The defective condition of the Simplex HV bone cement rendered it unreasonably dangerous and/or not reasonably safe, and the Simplex HV bone cement was in this defective condition at the time it left the hands of Defendants. The Simplex HV bone cement was expected to and did reach Ms. Feldman and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

45. The Simplex HV bone cement was used for its intended purposes and the product was not materially altered or modified prior to its use.

46. The Simplex HV bone cement is defective in design because of its propensity to loosen and cause patients unnecessary pain, failure of the device and repeat surgical procedures, including revision surgery, resulting in additional bone loss and other complications.

47. The Simplex HV bone cement is defective in design because the increased risk for component shifting, loosening, and failure requiring revision surgery at an unreasonably greater rate than other non-HV bone cements.

48. At or before the time the Simplex HV bone cement was released on the market and/or sold to Ms. Feldman, Defendants could have designed the Simplex HV bone cement to make it less prone to debonding and loosening, and there was a practical, technically feasible safer alternative design that would have prevented the harm Ms. Feldman suffered without substantially impairing the function of the device.

49. Ms. Feldman was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the Simplex HV bone cement. Further, in no way could Ms. Feldman have known that Defendants had designed, developed, and manufactured the Simplex HV bone cement in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

50. The Simplex HV bone cement is and was being used in the Defendants' intended manner at the time it was surgically implanted into Ms. Feldman and during the time it remained in Ms. Feldman.

51. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

52. Defendants knew or should have known that the Simplex HV bone cement would be implanted in patients and that physicians and patients were relying on them to furnish a suitable

product. Further, Defendants knew or should have known that patients in whom the Simplex HV bone cement would be used, such as Ms. Feldman, could be and would be affected by the defective design and composition of the Simplex HV bone cement.

53. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Ms. Feldman, and Defendants are therefore strictly liable for the injuries sustained by Ms. Feldman.

54. As a direct and proximate result of Defendants' placement of the defective Simplex HV bone cement into the stream of commerce and Ms. Feldman's use of the defective Simplex HV bone cement as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Ms. Feldman suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Ms. Feldman demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

## COUNT II
## STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

55. Ms. Feldman incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows.

56. At all times material hereto, Defendants were the manufacturers, designers, researchers, distributors, sellers, and/or suppliers of the Simplex HV bone cement and placed it in the stream of commerce in a condition which rendered it unreasonably dangerous due to its

propensity to result in early debonding and failure of the device. The subject product was unreasonably dangerous in construction or composition.

57. Alternatively, the Simplex HV bone cement purchased and implanted in Ms. Feldman was defective because it varied from Defendants' intended design and contained unreasonably dangerous conditions.

58. As a direct and proximate result of the defective condition of the Simplex HV bone cement, Ms. Feldman suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Ms. Feldman demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

## COUNT III
## STRICT PRODUCTS LIABILITY- FAILURE TO WARN

59. Ms. Feldman adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

60. At all times material hereto, Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced the Simplex HV bone cement into the stream of commerce knowing the cement would then be implanted in patients in need of a knee prosthesis. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including Ms. Feldman and Ms. Feldman's physicians, and therefore had a duty to warn of the risks associated with the use of the Simplex HV bone cement. Defendants breached this duty.

61. The Simplex HV bone cement was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the implantation of the Simplex HV bone cement and the comparative severity and duration of such adverse side effects.

62. The warnings, instructions, and information provided to the medical community and the public did not accurately reflect the symptoms, scope, or severity of potential side effects, specifically the risk of early mechanical loosening and debonding.

63. The Simplex HV bone cement was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential side effects.

64. Had Defendants reasonably and properly provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Ms. Feldman's physicians, would have used the Simplex HV bone cement, and no consumer, including Ms. Feldman, would have purchased and/or used the Simplex HV bone cement.

65. As a direct and proximate result of Defendants' conduct, Ms. Feldman has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Ms. Feldman demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

## COUNT IV
## BREACH OF EXPRESS WARRANTY

66. Ms. Feldman adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

67. Defendants expressly warranted to Ms. Feldman by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Ms. Feldman, and the general public, that the Simplex HV bone cement was safe, effective, fit and proper for its intended use.

68. For instance, Defendants expressly warranted that Simplex HV bone cement had the speed and fast-mixing times of other HV cements, while Simplex HV bone cement also had significantly equivalent strength and bone intrusion results as non-HV cements, including its own Simplex P bone cements.

69. The Simplex HV bone cement does not conform to those express representations because the Simplex HV bone cement is defective, is not safe, and has serious side effects.

70. Ms. Feldman and/or Ms. Feldman's physicians justifiably relied on Defendants' representations regarding the safety of the Simplex HV bone cement and Defendants' representations became part of the basis of the bargain.

71. As a direct and proximate result of Defendants' conduct, Ms. Feldman has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Ms. Feldman demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

## COUNT V
## BREACH OF IMPLIED WARRANTY

72. Ms. Feldman adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

73. Defendants were the sellers of the Simplex HV bone cement and sold the Simplex HV bone cement to Ms. Feldman and/or Ms. Feldman's physician to be used in Ms. Feldman's knee implantation surgery.

74. When the Simplex HV bone cement was used by Ms. Feldman's physician, the product was being used for the ordinary purpose for which it was intended.

75. The Simplex HV bone cement sold to Ms. Feldman was not merchantable because it was not fit for its ordinary purpose to adequately bond knee implantation devices.

76. The Simplex HV bone cement would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

77. Defendants have been put on notice that the Simplex HV bone cement is not fit for its ordinary purpose.

78. Defendants breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Ms. Feldman's body, which placed her health and safety at risk.

79. As a direct and proximate result of Defendants' conduct, Ms. Feldman has suffered and continues to suffer serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Ms. Feldman demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

## COUNT VI
## NEGLIGENCE

80. Ms. Feldman adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

81. Defendants had a duty to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling the Simplex HV bone cement.

82. Defendants failed to exercise ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the Simplex HV bone cement in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, including the loosening and debonding at the tibial plate, thereby breaching their duty to consumers, including Ms. Feldman.

83. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Negligently designing the Simplex HV bone cement in a manner which was dangerous to those individuals who had the device surgically implanted;

(b) Designing, manufacturing, producing, creating and/or promoting the Simplex HV bone cement without adequately, sufficiently, or thoroughly testing it;

(c) Failing to adequately and correctly warn Ms. Feldman and her physicians, hospitals, and/or healthcare providers of the dangers of the Simplex HV bone cement;

(d) Failing to recall their dangerous and defective Simplex HV bone cement at the earliest date that it became known that the device was, in fact, dangerous and defective;

(e) Advertising and/or marketing the use of the Simplex HV bone cement despite the fact that Defendants knew or should have known of its defects;

(f) Representing that the Simplex HV bone cement was safe for its intended purpose when, in fact, it was unsafe;

(g) Manufacturing the Simplex HV bone cement in a manner which was dangerous to those individuals who had it implanted; and

(h) Under-reporting, underestimating, and/or downplaying the serious danger of the Simplex HV bone cement.

84. Upon information and belief, Defendants continued to market, manufacture, distribute and/or sell the Simplex HV bone cement to consumers, including Ms. Feldman, despite the fact that Defendants knew or should have known that the Simplex HV bone cement caused unreasonable, dangerous defects, including a defective tibial plate design leading to early debonding and early failures, when there were safer alternative designs available.

85. At all material times, Defendants knew of the defective nature of the Simplex HV bone cement as set forth herein, and continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life.

86. As a direct and proximate result of Defendants' conduct, Ms. Feldman has suffered and continues to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Ms. Feldman demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff Rebecca Feldman prays for judgment against Defendants, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

(b) Judgment against Defendants for all compensatory allowable to Ms. Feldman;

(c) Judgment against Defendants for all other relief sought by Ms. Feldman under this Complaint;

(d) For reasonable attorneys' fees and costs;

(e) For pre-judgment interest; and

(f) For such further and other relief the Court deems just and equitable.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: June 1, 2018

Respectfully submitted,

**THE LAW OFFICES REYNOLDS AND REYNOLDS, PLLC**

**Russell R. Reynolds**
Texas State Bar No. 24009359
rusty@rrlfirm.com
**Debra S. Reynolds**
Texas State Bar No. 24043891
debra@rrlfirm.com
2591 Dallas Pkwy, Suite 300
Frisco, Texas 75034
Telephone: (214) 891-6606
Fax: (972) 731-4384

and

W. Roger Smith, III
Ryan J. Duplechin
**BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.**
(*Pending Admission Pro Hac Vice*)
Post Office Box 4160
Montgomery, Alabama 36103-4160

Phone: (334) 269-2343
Fax: (334) 954-7555
Email: Roger.Smith@BeasleyAllen.com
Ryan.Duplechin@BeasleyAllen.com

**COUNSEL FOR PLAINTIFF**